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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/582,695	03/21/2007	David C. Greenspan	13791-23	6560

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EXAMINER	
KOSINSKI, IRINA Y	

ART UNIT	PAPER NUMBER
1612	

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10/27/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/582,695	GREENSPAN ET AL.	
	Examiner	Art Unit	
	IRINA KOSINSKI	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 September 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *06/13/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I, corresponding to the claims 1-18 in the reply filed on 09/08/2009 is acknowledged. The traversal is on the ground that inventions of Group I and II relate to a single general inventive concept because they share the special technical feature of a composition comprising bioactive glass, which makes contribution over the prior art in view of Stoor et al. (US 6190643) since the concentration of bioactive glass in the prior art composition is significantly different (40-80%). In view of the presented argument, the Restriction Requirement is hereby expressly withdrawn. Claims 1-34 are currently under consideration.

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-31 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for reducing plaque or plaque build-up and gingivitis, does not reasonably provide enablement for prevention of plaque or plaque build-up and gingivitis. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

To be enabling, the specification of the patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. In re Wright, 999 F.2d 1557, 1561 (Fed. Cir. 1993). Explaining what is meant by "undue experimentation," the Federal Circuit has stated:

> The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the claimed invention. PPG v. Guardian, 75 F.3d 1558, 1564 (Fed. Cir. 1996).[1]

The factors that may be considered in determining whether a disclosure would require undue experimentation are set forth by In re Wands, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,
2) the amount of direction or guidance provided,
3) the presence or absence of working examples,
4) the nature of the invention,
5) the state of the prior art,
6) the relative skill of those in the art,
7) the predictability of the art, and
8) the breadth of the claims.

These factors are always applied against the background understanding that scope of enablement varies inversely with the degree of unpredictability involved. In re Fisher, 57 CCPA 1099, 1108, 427 F.2d 833, 839, 166 USPQ 18, 24 (1970). Keeping

that in mind, the Wands factors are relevant to the instant fact situation for the following reasons:

1. The nature of the invention, state and predictability of the art, and relative skill level

The invention relates to methods and compositions for preventing or reducing plaque or plaque build-up and gingivitis in an individual. The relative skill of those in the art is high, that of an MD or PHD. That factor is outweighed, however, by the unpredictable nature of the art. According to the American Dental Association (http://www.ada.org/public/topics/cleaning_faq.asp), plaque is a sticky film of bacteria that forms on teeth and gums. The bacteria present in the plaque are all naturally present in the oral cavity. Plaque can trigger gingivitis since it irritates the gums, making them red, tender, and eventually causing the gums to pull away from teeth. Plaque is removed by brushing and cleaning between teeth every day. There is no indication in the prior art that plaque or its formation could be prevented.

2. The breadth of the claims

Pages 6-7, paragraphs 0019, 0021 and 0024 define "prevention of plaque", "prevention of plaque build-up" and "prevention of givgivitis". That being noted, instant specification still provides no limiting definition of the term "prevention", therefor the term

[1] As pointed out by the court in In re Angstadt, 537 F.2d 498 at 504 (CCPA 1976), the key word is "undue", not "experimentation".

will be interpreted expansively. The term "prevention" may vary widely in meaning, from "preventing" plaque/plaque build-up/gingivitis from occurring to "preventing" it from progressing. Nor is the term limited by any time frame.

The claims are thus very broad insofar as they suggest that one will not experience plaque/plaque build-up/gingivitis when brushing with the toothpaste comprising bioactive glass; that should one get plaque/plaque build-up/gingivitis , it will not worsen; or that following its treatment, it will not recur. While such "prevention" might theoretically be possible under strictly controlled laboratory conditions, as a practical matter it is nearly impossible to achieve in the "real world" in which patients live.

3. The amount of direction or guidance provided and the presence or absence of working examples

The specification provides no direction or guidance for practicing the claimed invention in its "full scope". No reasonably specific guidance is provided concerning useful therapeutic protocols for preventing plaque/plaque build-up/gingivitis, other than the reduction in numbers of common oral pathogens in vitro and improvement of oral health (reduction of gingival bleeding and reduction of in supra-gingival plaque) in vivo. The latter is corroborated by the working examples.

4. The quantity of experimentation necessary

Because of the known unpredictability of the art, and in the absence of experimental evidence, no one skilled in the art would accept the assertion that the instantly claimed agents could be predictably used to prevent plaque/plaque build-up/gingivitis in an individual's oral cavity, as inferred by the claims and contemplated by the specification. Accordingly, the instant claims do not comply with the enablement requirement of §112, since to practice the claimed invention in its "full scope" a person of ordinary skill in the art would have to engage in undue experimentation, with no reasonable expectation of success.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims recite the limitation "less than about"/"more than about". The term "less"/"more" delineates only numerical values that are less/more than the recited value where the term "about" may be less than or more than the recited value. Because of the conflict of terms, it is unclear which term is limiting. See also MPEP 2173.05(b) (citing Amgen v. Chugai, 18 USPQ2d 1016 (Fed. Cir. 1991), in which the phrase "at least about" was held indefinite).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gates et al. (US 5882630) in view of Litkowski et al. (WO 99/13852)

Gates et al. disclose a dentifrice composition that is suitable as a vehicle for materials that are incompatible with an aqueous environment, said composition comprising carboxyvinyl polymer, a humectant, polyethylene glycol and a dentally acceptable abrasive (abstract). Examples 1-5 (columns 4-5) disclose compositions that encompass instant claims 1, 4-8, 10, 13-17, 20-32 and 34 insofar that they teach the same non-aqueous carrier that is used in the instant invention. The pH of the formulation when diluted in the ratio of 3:1 with water should be less than 8.0 (column 4, lines 18-19).

The dentifrice compositions disclosed by Gates et al. do not comprise bioactive glass particles; however reference teaches that non-aqueous compositions may suitably contain other materials which are unstable and incompatible with an aqueous environment (column 1, lines 5-10).

Litkowski et al. disclose methods and compositions for whitening teeth. Various embodiments of the compositions include particles of bioactive glass in the range from less than about 90 micron to less than about 5 micron (claims 5-8). Oral hygiene compositions comprise between 0.1 to 50% by weight, preferably 1 to 25% by weight of bioactive glass particles. The most preferably concentration of bioactive glass in compositions for whitening teeth is 5 to 10% by weight (page 4, lines 14-16). The compositions may be formulated as toothpastes, containing usual carriers, such as humectants, abrasives, etc. (page 4, lines 10-11, 17-21).

Litkowski et al. do not specifically teach a composition comprising bioactive glass having an average particle size of less than about 20 microns, nor do they disclose the same preferred concentration of the particles in the composition as in the instant claims 9,18 and 33 (from about 2 to about 5% by weight). Having said that, one skilled in the art would readily recognize the general working conditions fairly suggested thereby, particularly the low concentrations of the bioactive glass particles and small particle size suggested therein(from 90 to 5 micron), and would be able to ascertain useful values for same using no more than routine experimentation.

Generally, it is *prima facie* obvious to select a known material for incorporation into a composition, based on its recognized suitability for its intended use. See MPEP

2144.07. Accordingly, it would have been prima facie obvious to the one skilled in the art at the time of invention to combine teachings of Gates et al. concerning a dentifrice composition that is suitable as a vehicle for materials that are incompatible with an aqueous environment with the teaching of Litkowski et al. concerning compositions that contain low concentrations of bioactive glass and may be formulated into toothpaste. Moreover, as discussed by the instant specification (page 3, paragraph 0009), when the concentration of the bioactive glass in such compositions is relatively high (from 40 to 80% by weight) exposing such compositions to water results in a significant pH increase of the composition (about 3.9 pH units). By contrast, the compositions disclosed by Litkowski et al. comprise relatively low concentrations of bioactive glass particles (most preferred from 5 to 10 % by weight of the composition). Accordingly, one skilled in the art would reasonably expect to inherently see a correspondingly lower increase in the pH after introducing such composition to the oral cavity, i.e., less than 1.5 pH units as claimed instantly.

Instant claims 2-3 and 11-12 disclose methods for using compositions comprising bioactive glass. The compositions are toothpastes, the methods are essentially instructing the individuals to brush their teeth with toothpaste for 2 minutes, which is not novel in itself since it is generally recommended by dentists.

Technological Background Material

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Stoor et al. disclose a method for reduction of viability of detrimental oral microorganisms and for prevention of dental caries and/or gingivitis in an individual (abstract). Background of the Invention section (column 1, lines 22-63) teaches the "working mechanism" of bioactive glass ions. It discusses several uses of bioactive glasses, including their antibacterial activity (lines 43-53).

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to IRINA KOSINSKI whose telephone number is (571)270-1334. The examiner can normally be reached on Monday through Thursday 7:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fred Krass can be reached on (571)272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/IRINA KOSINSKI/
Examiner, Art Unit 1612

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612